



AF/1743 #

TRANSMITTAL OF APPEAL BRIEF (Large Entity)

Docket No.
2693In Re Application Of: JOHN L. ROBERTSON; JANE TSAI; LAWRENCE C. McPHEE; STEVEN S. BACHAND;
ROBERT L. GRENZ; DENNIS BLEVINSSerial No.
09/834,769Filing Date
04/13/2001Examiner
ALEXANDER LYLE

Group Art Unit

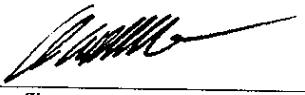
1743

Invention: MULTIPLE ANALYTE ASSAYING DEVICE WITH A MULTIPLE SAMPLE
INTRODUCTION SYSTEMRECEIVED
DEC 24 2003
TC 1700TO THE COMMISSIONER FOR PATENTS:

Transmitted herewith in triplicate is the Appeal Brief in this application, with respect to the Notice of Appeal filed on
OCTOBER 22, 2003

The fee for filing this Appeal Brief is: \$330.00

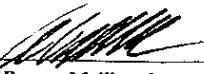
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SignatureDated: DECEMBER 11, 2003

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2693



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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DEC 24 2003
TC 1700

Applicant: John L. Robertson, et al.) Examiner
Serial No.: 09/834,769) Lyle, A.
Filed: 04/13/2001)
For: MULTIPLE ANALYTE ASSAYING) Art Unit
DEVICE WITH A MULTIPLE SAMPLE) 1743
INTRODUCTION SYSTEM)

December 2003

BRIEF ON APPEAL

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12/11/03
(DATE SIGNED)

WALTER A. HACKLER
WALTER A. HACKLER
REG. NO. 27,792

Dear Sir:

This appeal is taken from a rejection of the claims of the hereinabove referenced Design Patent Application in a final Office Action mailed August 13, 2003; oral hearing is waived.

12/16/2003 MDAMTE1 00000013 09834769

01 FC:1402

330.00 OP REAL PARTY OF INTEREST

The present application is presently assigned to Varian, Inc. as evidenced by an assignment recorded on June 5, 2002 on reel 012958 on frame 0357 and an assignment was recorded on November 13, 2002 on reel 013484 and frame 0014.

RELATED APPEALS AND INTERFERENCES

There are no appeals or interferences on applications related to the present application.

STATUS OF CLAIMS

<u>Claims</u> (See Appendix A)	<u>Status</u>
1 and 22-25	Rejected under 35 USC 102(b) on the basis of U.S. 5,656,503 to May, et al.
21	Rejected under 35 USC 103(a) on the basis of U.S. 6,203,757 to Lu, et al. or U.S. 5,656,507 to May, et al. along or in view of U.S. 5,976,896 to Cipkowski.

STATUS OF POST FINAL AMENDMENT

None

CONCISE SUMMARY OF THE INVENTION

The present invention provides for a multiple analyte assaying device which includes a casing having a pocket extending outwardly from the casing for capturing and containing a predetermined volume of fluid specimen to be assayed.

A sample pad and a feed element are provided for controlling a release rate of fluid sample from the pocket. The feed element includes a generally planar surface pressed against the sample pad and at least one feed inlet through the planar surface for providing fluid communication between the sample pad and the pocket. The feed element is disposed with sufficient pressure between the generally planar surface and the sample pad in order to control a rate of fluid sample release from the pocket. A testing assembly is also provided in a casing for assaying the release of fluid sample from the pocket.

ISSUES PRESENTED FOR REVIEW

ANTICIPATION

The Examiner has rejected claims 1 and 22-25 on the basis of May, et al.

OBVIOUSNESS

The Examiner has rejected claim 21 on the basis of Lu, et al. or May, et al. alone or in view of Cipkowski.

GROUPING OF CONTESTED CLAIMS

A request for separate review by the Board with regard to patentability under the anticipation rejection is made for the following groups:

Group 1, claims 1 and 25 including a feed element having a planar surface pressed against a sample pad and at least one feed inlet, the planar surface being pressed against the sample pad to control a rate fluid sample release;

Group 2, claim 22 including a feed inlet slot in the planar surface;

Group 3, claim 23 including means for supporting said casing on a generally horizontal surface with the pocket disposed in a spaced apart relationship with the generally horizontal surface; and

Group 4, claim 24 including a plurality of spaced apart test strips.

ARGUMENT

Rejection under 35 USC 102(b) Group 1 claims.

The Examiner has rejected claims 1 and 25 under 35 USC 102(b) as being anticipated by May, et al. In this rejection, the Examiner states that May, et al. teaches an analytical device contained within a plastic casing that has been read on the claimed "casing". The Examiner further states that the sample receiving member (506) has been read on the claimed "sample pad" and the dry porous carrier (510) has been read on the claimed "feed element".

The Examiner further states that both member (506) and carrier (510) are in fluid communication which has been read on the claimed "pressed" relationship.

The test for anticipation requires that a single prior art referenced discloses, expressly or under principles of inherency, each and every element of the claimed invention.

RCA Corp. v. Applied Digital Data Systems, Inc., 221 USPQ 385 (Fed. Cir. 1984). In re Sun, 31 USPQ 2d 1451 (CAFC 1993); Advanced Display Systems, Inc. v. Kent State University, 540 USPQ 2d 1673 (CAFC 2000).

Further, the Appellants submit that anticipation must meet strict standards, and unless all of the same elements are found in exactly the same situation and united in the same way to form identical function in a single prior art reference, there is no anticipation. Tights, Inc. v. Acme-McCary Corporation, et al., 191 USPQ 305 (CAFC 1976).

Bearing in mind this criteria, independent claims 1 and 25 under appeal include a sample metering means for controlling a release rate of fluid sample from a pocket with the sample metering means including a sample pad and a feed element having a generally planar surface pressed against the sample pad and at least one feed inlet through the planar surface for providing fluid communication between the sample pad and the pocket.

As specifically claimed, the fluid element is disposed with sufficient pressure between the generally planar surface and the sample pad in order to control a rate of fluid sample release from the pocket.

Clearly, there is no such structure taught, suggested or inferred by the May, et al. reference which functions in a manner similar to the structure of the present invention and results in a control rate of fluid sample and release from a pocket containing sample.

May, et al. teaches a first assay test strip embodiment 10, shown in the Figures 1-5, which teaches a rectangular strip including a lower end 11 for contact with a liquid sample, see Figure 2.

As shown in Figures 3-5, May, et al. teaches a device having a flat rectangular body 30 having a bottom edge 35 which incorporates a lateral aperture in which the bottom end 11 of the strip 10 lies.

In operation, the bottom end 33 of the body 30 is immersed in a liquid sample so that the liquid sample can be absorbed by the bottom end 11 of the test strip 20 and rise by a capillary action to the top 17 of the test strip and into the sink 18. See column 10, line 66 through column 11, line 3. This is no structure for controlling rate of fluid sample release such as the planar surface in accordance with the present invention.

Accordingly, there is no structure taught in this embodiment of May, et al. which is at all similar to the Appellants feed element which includes a generally planar surface pressed against the sample pad.

With reference to Figures 6 and 7 of May, et al., there is taught another test device which includes an elongate body 200 terminating at its lower end 201 in a small integral receptacle 202 which can hold a predetermined volume of liquid sample. The front face 203 of the body 200 incorporates two apertures or windows 204 and 205 located above one another.

As set forth in column 11, beginning at line 31 in operation, a liquid sample is applied to the bottom of the device and a predetermined volume of the sample fills the receptacle 202. From the receptacle 202, the liquid sample rises by capillary action through the test strip 206 and conveys the label reagent from zone 208 to the two circular zones 209 and 210.

May, et al. in this embodiment teaches the use of a receptacle and a test strip for moving a sample through capillary action. There is no teaching or suggestion of a feed element having a generally planar surface pressed against a sample pad as is presently claimed.

Accordingly, this embodiment also does not teach any structure which functions in a manner similar to the structure of the claimed invention which results in controlling a rate of fluid sample release from a pocket.

Yet another embodiment is shown by May, et al. in Figures 8-10 which includes a housing or casing 500 which contains a porous member 506 contacting a strip porous carrier material 510 with an overlap to insure that there is adequate contact between these two materials. A liquid

sample applied to the member 506 can permeate the member 506 and progress into the strip 510 which extends farther back into the housing, see column 12, lines 7-16. A cap 503 is fitted onto the housing for covering the porous member 506.

As set forth in column 12, beginning at line 44 in operation, the protective cap 503 is removed from the holder and the membrane 506 is exposed to a liquid sample by being placed in the urine stream in the case of a pregnancy test.

The Appellants again submit there is no structure taught by this embodiment in May, et al of a feed element having a planar surface pressed against a sample pad and at least one feed element through the planar surface for providing fluid communication between the sample pad and a pocket in order to control a rate of fluid sample release from the pocket.

Figures 11 and 12 illustrate yet another embodiment of the May, et al. invention which includes a flat rectangular casing 600 incorporating a generally disposed rectangular aperture 601 adjacent the left hand 602 and two further apertures 603 and 604 near the midpoint of the device and arranged such that the apertures 601, 603, and 604 lie in the central longitudinal axis of the device. (Column 14, lines 3-9)

As set forth in column 14, beginning at line 31, in operation an aqueous sample can be placed through the aperture 601 by means of a syringe, to saturate the porous

receiving members 605 thereafter the aqueous sample can permeate the test strip and after an appropriate time, the test result can be observed through the aperture 603 and 604.

Clearly, there is no teaching by May, et al. in this embodiment of the structure presently claimed in the present application, namely a feed element having a generally planar surface pressed against the sample pad and at least one feed inlet through the planar surface for providing fluid communication with the sample pad and the pocket in order to control a rate of fluid sample release from the pocket.

May, et al. teaches a further embodiment as illustrated in Figures 13 and 14 which includes a device comprising a rectangular casing 700 having in its upper surface 701 a rectangular aperture 702. One endwall 703 of the device incorporates an aperture 704 through which a porous test element communicates with the exterior end device. The aperture 702 is situated in the surface 701 at a point relatively remote from the end 703 containing the aperture 704.

An operation is set forth in column 14, beginning at line 61 wherein it is stated that the first test element can be exposed to an aqueous sample by dipping end the 703 of the casing 700 into a vessel containing the sample. The liquid sample will then permeate the length of the test strip 705 taking a label reagent from zone 706 and passing through zone 707 with a label reagent can be bound, e.g.

through a "sandwich" reaction involving an analyte in the sample.

The Appellants submit that there is no teaching of the structure presently claimed which, as hereinabove noted repeatedly, includes a feed element having a planar surface pressed against a sample pad and at least one feed inlet through the planar surface for providing fluid communication between the sample pad and the pocket in order to control a rate of fluid sample release from the pocket.

In view of the fact that the feed element in accordance with the present invention as presently claimed is not taught by May, et al., there cannot be any anticipation under 35 USC 102(b).

Further, there is no teaching of May, et al. which can be construed as inherently teaching the structure of the present invention since the embodiments of May, et al. rely on exposure of a porous element for conducting fluid by capillary action and have no means for introducing specimen other than by simple capillary absorption.

ARGUMENT

Rejection under 35 USC 102(b) Group 2 claims.

The Board is specifically requested to separately consider the rejection of claim 22 rejected by the Examiner under 35 USC 102(b).

In view of the criteria hereinabove set forth with regard to anticipation, the Appellants submit that no structure of May, et al. hereinabove described in any of the embodiments provide for a feed inlet which comprises a slot in a generally planar surface in order to provide controlled release of fluid in said pocket to the feed element.

In view of the fact that May, et al. does not teach any planar surface, it would be impossible to literally or inherently teach a slotted feed inlet through the planar surface, as defined in the claim 22. Accordingly, the Appellants respectfully request the Board to independently consider the patentability of claim 22 under the hereinabove set forth criteria for anticipation under 35 USC 102(b) in view of the specific structure set forth in claim 22. The argument with regard to the rejection of claims 21 and 25 is repeated herewith.

ARGUMENT

Rejection under 35 USC 102(b) Group 3 claims.

The Appellants respectfully request specific and separate consideration of the rejection of claim 23 by the Examiner under 35 USC 102(b).

Claim 23 provides for means for supporting a casing on a general horizontal surface with a pocket disposed in a spaced apart relationship with a generally horizontal surface.

Bearing in mind the criteria hereinabove set forth for anticipation under 35 USC 102(b), none of the embodiments disclosed by May, et al. have any structure similar to the means for supporting the cases in the generally horizontal surface in accordance with claim 23 in order to disposed the pocket in a spaced apart relationship with the generally horizontal surface.

As illustrated in Figure 5, the means for supporting the casing on a generally horizontal surface includes a rail 84 which prevents "wet" contact of the device 10 with a table or a countertop 88 while assaying is taking place. As set forth in the original specification on page 14, beginning at line 10, the rail 84 is structured to elevate the pocket portion 42 above the surface 88 upon which the device is placed when the device 10 is disposed in the substantially horizontal position.

It must be clear that no such structure is taught, suggested and certainly not anticipated by the May, et al. In view of this lack of teaching of May, et al., of means for supporting the casing on a generally horizontal surface with the pocket disposed in a spaced apart relationship with the generally horizontal surface, a rejection under 35 USC 102(b) is unsupportable. The Appellants specifically request separate consideration of the rejection of claim 23 under 35 USC 102(b).

ARGUMENT

Rejection under 35 USC 102(b) of Group 4 claims.

The Examiner has rejected claim 24 under 35 USC 102(b). The Appellants specifically requests separate consideration of the Board of claim 24 which structure includes a plurality of spaced apart tests strips each communicating with the sample metering means.

In view of the fact that May, et al. only teaches a single test strip, there is no anticipation under 35 USC 102(b) based upon the hereinabove set forth criteria in view of this lack of teaching by May, et al., the Appellants respectfully request the Board to separately consider the rejection of claim 24 under 35 USC 102(b).

ARGUMENT

Rejection of claim 21 under 35 USC 103(a).

Claim 21 has been rejected by the Examiner under 35 USC 103(a) as being unpatentable over Lu, et al. of May, et al. alone or in view of Cipkowski.

In this rejection, the Examiner acknowledges that the cited art is silent to a "plurality of spaced apart feed inlets". The Examiner relies on St. Regis Paper Company v. Bemis Company, Inc., (193 USPQ 8, 11) that duplication of parts for a multiplied effect is within the skill of the artisan and concludes it would have been within the skill of the art to modify Lu, et al. or May, et al. and provide a plurality of feed inlets to gain the advantage of multiple different tests being performed simultaneously.

The Examiner further states that Cipkowsky teaches that it is advantageous to use a test device having multiple feed inlets to simultaneously test for multiple analytes which saves time and money for the lab. The Examiner again concludes it would have been within the skill of the art to modify Lu, et al. or May, et al. in view of Cipkowsky to use a plurality of spaced apart feed inlets to gain the above advantages.

The St. Regis Paper Company citation refers to the use of multiple layers to achieve the effect of many bags when one bag has been known in the bag industry for many years. The court concluded that the Lockey bag is only entitled to a patent if the fusion of old elements that comprise the Poppe patent and the old elements of multiple layering created a synergistic combination. (Page 11) The court concluded that while the additional multiple applies to the concept of the Poppe bag undoubtedly made it stronger and even may have been necessary to make this type of bag commercially feasible, it is not the type of innovation for which a patent monopoly is to be granted.

In summary, the St. Regis Paper Company citation with regard to a duplication of parts for a multiplied effect is old when the original single effect was well known.

This must be contrasted with the case at hand in which the at least one feed inlet through a planar surface for providing fluid communication between the sample pad and the pocket is not known in the art. Since a single feed inlet is not known in the art, the argument that a

plurality of such feed inlets is known in the art is without foundation.

The Appellants submit that the St. Regis Paper Company citation does not support the Examiner's conclusion. Basically, the St. Regis Paper decision states that the multiplicity of a known element is not patentable in and of itself. In the case at hand, the element, namely, the feed inlet through a planar surface, as claimed, is not taught or suggested by the art, as admitted by the Examiner. Accordingly, the Appellants submit that the Examiner has not made a *prima facie* case of obviousness.

The Appellants submit that merely concluding that an invention would have been obvious does not discharge the Examiner from the burden of providing the requisite factual basis and establishing the requisite motivation to support the conclusions of obviousness. Ex parte Stern, 13 USPQ 2d 1379 (BPAI 1989). "It is facts which must support the legal conclusion of obviousness", Ex parte Crissy, Spano and Wolff, 201 USPQ 689 (POBd App. 1976). The patent office cannot "resort to speculation...to supply deficiencies and the factual basis". In re Warner, 154 USPQ 173 (CCPA 1967).

The Examiner has not provided any factual basis or motivation for providing the feed element in accordance with claim 21 which includes a generally planar surface pressed against a sample pad and a plurality of spaced apart feed inlets in the generally planar surface in order to provide controlled release of fluid in the pocket to the feed element. A matter of choice or design cannot be

dismissed absent some reason why a person skilled in the art would find it obvious to depart from the structure of the cited art. In re Bezombes, Peyches and Tissier, 164 USPQ 387 (CCPA 1970).

The Examiner has presented no factual basis, by way of cited art, showing or suggesting the structure of claim 21.

In view of the hereinabove presented arguments, the Appellants respectfully request the Board to reverse the Examiner's rejection of claims 1 and 22-25 under 35 USC 102(b) and rejection of claim 21 under 35 USC 103(a).

Respectfully submitted,



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